DEC - 1 2011

SECTION 5
510(k) SUMMARY

510(k) Notification K113032

GENERAL INFORMATION

Applicant:

Spiracur Inc.
1180 Bordeaux Drive
Sunnyvale, CA 94089
U.S.A.
Phone: 408-701-5300
Fax: 408-701-5301

Contact Person:

Sarah L. Canio
Experien Group, LLC
755 N. Mathilda Avenue, Suite 100
Sunnyvale, CA 94085
U.S.A.
Phone: 408-400-0856 ext. 109
Fax: 408-400-0865
Email: sarah@experiengroup.com

Date Prepared: October 11, 2011

DEVICE INFORMATION

Trade Name:

SNaP® Wound Care System

Generic/Common Name:

Non-powered suction apparatus device intended for negative pressure wound therapy

Classification:

21 CFR§878.4683, Class II

Product Code:

OKO

SECTION 5
510(k) SUMMARY

PREDICATE DEVICE(S)

- Spiracur SNaP® Wound Care System (K111393)
- Spiracur SNaP® Wound Care System (K112341)
- KCI USA, Inc. V.A.C.® Therapy Systems (K091585)

DEVICE DESCRIPTION

The SNaP® Wound Care System ("SNaP System") is a portable, non-powered suction device intended for wound management via application of negative pressure to the wound bed for removal of fluids, including wound exudate, irrigation fluids and infectious materials.

INDICATIONS FOR USE

The SNaP® Wound Care System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The SNaP® Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

SUBSTANTIAL EQUIVALENCE

There have been no changes made to the cleared SNaP System as result of the proposed labeling changes. The expanded indications for use to include venous ulcers in the labeling for the SNaP System are substantially equivalent to the indications for use for the predicate device, the KCI V.A.C.® Therapy Systems. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness with regard to the treatment of venous ulcers. Thus, the SNaP System is substantially equivalent to the predicate devices.

DEVICE TESTING

The SNaP System is an existing device to which no design changes have been made as a result of the labeling changes. As such, no further testing has been conducted.

SUMMARY

The SNaP System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spiracur, Inc.
% Experien Group, LLC
Ms. Sarah Canio
755 N. Mathilda Avenue, Suite 100
Sunnyvale, California 94085

DEC - 1 2011

Re: K113032
Trade/Device Name: The SNaP® Wound Care System
Regulation Number: 21 CFR 878.4683
Regulation Name: Non-Powered suction apparatus device intended for negative pressure wound therapy
Regulatory Class: II
Product Code: OKO
Dated: November 21, 2011
Received: November 22, 2011

Dear Ms. Canio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113032

Device Name:

Indications For Use:

The SNaP® Wound Care System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The SNaP® Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113032